Supreme Court, U. S.
FILED
FEB 10 1979
MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court

OF THE

United States

OCTOBER TERM, 1978

No. 78-421

GEORGE KIEVLAN, et al.,
Appellees,

vs.

DAHLBERG ELECTRONICS, INC., et al.,
Appellants

On Appeal from the Court of Appeal of the State of California First Appellate District

APPELLANTS' BRIEF IN OPPOSITION TO MOTION TO DISMISS OR AFFIRM

MICHAEL P. CARBONE
JORDAN, LAWRENCE, DAWSON & CARBONE
235 Montgomery Street, Suite 1249
San Francisco, California 94104
Telephone: (415) 392-4142
Attorneys for Appellants Dahlberg Electronics, Inc., and Detection Sciences, Inc.

BOWNE-PERNAU WALSH • 1045 SANSOME ST. • S.F., CA 94111 • (415) 981-7882

SUBJECT INDEX

	Page
Reply to appellees' statement of the case	1
Argument	4
I	
The doctrine of primary administrative jurisdiction does not apply	4
A. The question whether the statute has been preempted is for the Court and not for the F.D.A.	5
B. A stay of the appeal is not required	7
C. The appeal should not be dismissed on the basis of the primary administrative jurisdiction doctrine	9
II	
The statute has been pre-empted	10
A. Specific counterpart regulations have been adopted by the F.D.A.	11
B. The federal law and regulations are directly concerned with advertising	12
C. It is impossible to comply with both the state law and the federal law and regulations	13
D. The California statute relates to the effectiveness of hearing aids as well as to the advertising thereof	15
E. The state statute is not to be deemd exempt from pre-emption	16
F. Regulation of hearing aid advertising is within the jurisdiction of the F.D.A.	16
III	
The statute infringes upon the right to freedom of speech	18
A. The Court of Appeal passed upon the issue	18
B. There is no compelling state interest sufficient to justify the denial of free speech	19
C. Appellant's interest is not contrary to the interests of the hearing aid user	20
D. Appellant should not be required to apply for permission to advertise under Health and Safety Code Section 26465	21
Conclusion	22

TABLE OF AUTHORITIES CITED

Cases

Page

Federal

Amalgamated Meat Cutters & Butcher Workmen v. Jewel Tea Co. (1965) 381 U.S. 676, 14 L.Ed.2d 640, 85 S.Ct. 1596 ..... 8, 9

Armour & Co. v. Alton R. Co. (1941) 312 U.S. 195, 85 L.Ed. 771, 61 S.Ct. 498 5

Chambers v. Mississippi (1973) 410 U.S. 284, 35 L.Ed.2d 297, 93 S.Ct. 1038 19

Far East Conference v. U.S. (1952) 342 U.S. 570, 96 L.Ed. 576, 72 S.Ct. 492 5

Federal Power Com. v. Louisiana Power and Light Co. (1972) 406 U.S. 621, 32 L.Ed.2d 369, 92 S.Ct. 1827 7

General American Tank Car Corp. v. El Dorado Terminal Co. (1940) 308 U.S. 422, 84 L.Ed. 361, 60 S.Ct. 325, reh. den. 309 U.S. 694, 84 L.Ed. 1035, 60 S.Ct. 465 10

Great N.R. Co. v. Merchants Elevator Co. (1922) 259 U.S. 285, 66 L.Ed. 943, 42 S.Ct. 477 5

International Brotherhood of Boilermakers, etc. v. Hardeman (1971) 401 U.S. 233, 28 L.Ed.2d 10, 91 S.Ct. 609, reh. den. 402 U.S. 967, 29 L.Ed.2d 132, 91 S.Ct. 1607 9

Jones v. Rath Packing Co. (1977) 430 U.S. 519, 51 L.Ed.2d 604, 97 S.Ct. 1305 12

Louisville & N.R. Co. v. F. W. Cook Brewing Co. (1912) 223 U.S. 70, 56 L.Ed. 355, 42 S.Ct. 189 5

Mitchell Coal & Coke Co. v. Pennsylvania R. Co. (1913) 230 U.S. 247, 57 L.Ed. 1472, 33 S.Ct. 916 10

New York ex rel. Bryant v. Zimmerman, 278 U.S. 63 19

Public Utilities Com. v. United States (1958) 355 U.S. 534, 2 L.Ed.2d 470, 78 S.Ct. 446 8

Ricci v. Chicago Mercantile Exchange (1973) 409 U.S. 289, 34 L.Ed.2d 525, 93 S.Ct. 573 9

Street v. New York (1969) 394 U.S. 576, 22 L.Ed.2d 572, 89 S.Ct. 1354 19

Texas & P.R. Co. v. Abilene Cotton Oil Co. (1907) 204 U.S. 426, 51 L.Ed. 553, 27 S.Ct. 350 ..... 5, 6

United States v. Michigan National Corp. (1974) 419 U.S. 1, 42 L.Ed.2d 1, 95 S.Ct. 10 10

United States v. Western R.R. Co. (1956) 352 U.S. 59, 1 L.Ed.2d 126, 77 S.Ct. 161 9

Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc. (1976) 425 U.S. 748, 48 L.Ed.2d 346, 96 S.Ct. 1817 ..... 19, 20

TABLE OF AUTHORITIES CITED

Cases

Page

State

American Soc. of Composers, Authors and Publishers v. Superior Court of Los Angeles County (1962) 24 Cal. Rptr. 772, 207 C.A.2d 676 4

Brewer v. Reliable Automotive Co. (1966) 49 Cal.Rptr. 498, 240 C.A.2d 173 4

House v. Lala (1960) 4 Cal.Rptr. 366, 180 C.A.2d 412 4

New Jersey Guild of Hearing Aid Dispensers, et al. v. Long (1977) 75 N.J. 544, 384 A.2d 795 ..... 7, 12

New York State Hearing Aid Society v. State of New York (E.D.N.Y., March 10, 1978) 7

Sontag Chain Stores Co. v. Superior Court (1941) 18 Cal.2d 92, 113 P.2d 689 10

Constitutions

United States Constitution:

First Amendment 10, 14, 21

Regulations

21 C.F.R. Section 801.421 20

Section 808.1(d) 11

40 Fed.Reg. 26646 17

42 Fed.Reg. 9286 ..... 13, 17

43 Fed.Reg. 33182 15

Statutes

California Business & Professions Code:

Section 3305 21

California Health and Safety Code:

Section 26002 ..... 12, 13

Section 26463 ..... 11, 21

Section 26465 21

21 U.S.C. Section 352(r) 11, 13, 14, 16

Section 360k 15

Section 360k(a) 16

Section 360k(b) 7, 16

Texts

3, K. Davis, Administrative Law Treatise, sec. 19.01 6

Other Authorities

Annotation, Primary Administrative Jurisdiction, 38 L.Ed.2d 796 6

IN THE

Supreme Court

OF THE

United States

OCTOBER TERM, 1978

No. 78-421

GEORGE KIEVLAN, et al.,
Appellees,

vs.

DAHLBERG ELECTRONICS, INC., et al.,
Appellants

On Appeal from the Court of Appeal
of the State of California
First Appellate District

APPELLANTS' BRIEF IN OPPOSITION TO MOTION TO DISMISS OR AFFIRM

REPLY TO APPELLEES' STATEMENT OF THE CASE

In their "Statement of the Case" appellees attempt to characterize appellant's advertising as part of a campaign to defraud the hard of hearing by selling them expensive and unnecessary hearing aids. They claim to have "pre-

sented facts demonstrating the harm caused by [Dahlberg's] advertisements," including "serious and repeated incidents of abusive sales practices used by the local Dahlberg dealer, resulting in the plaintiffs being sold expensive hearing aids which could not or did not help them, and which in several cases were not medically appropriate." (Motion, pp. 6-7). In sole support of this statement, they refer the Court to certain declarations under penalty of perjury, including their own, which are included in the record. (C.T. 32-91). An examination of these declarations will show that appellees' claims are without factual support and are an attempt to mislead the Court.

Appellees' declarations alleged fraudulent practices by one John Maier, a hearing aid dispenser in Santa Cruz County. Mr. Maier's practices, whatever they may have been, had nothing to do with appellant or its advertising. The parties stipulated in the superior court that " . . . no agency relationship existed between the defendants John Maier, LeRoy Stacy, the Professional Hearing Aid Center aka Monterey Peninsula Hearing Aid Center and the defendants Dahlberg Electronics, Inc. or Detection Sciences, Inc." (See Stipulation and Order, C.T. 119-120). Therefore it is misleading to refer to Mr. Maier as the "local Dahlberg dealer."

No declaration was submitted from any of the appellees or from any other person stating that he or she had read a Dahlberg advertisement and had been led thereby to purchase an unnecessary hearing aid or to forego necessary diagnosis and treatment.

1. The Declaration of George Kievlan makes no mention at all of any advertising. (C.T. 32-35).

2. The Declaration of Eris Gofinch states that she saw a piece of advertising, but does not identify it as Dahlberg advertising. (C.T. 45-49).

3. The Declaration of Charles Harrold states that he received a piece of Dahlberg advertising in the mail and responded to it by sending in a post card. But he makes no complaint about the advertising as such, only about the practices of Mr. Maier. (C.T. 53-60).

4. The Declaration of Mary Walker makes no mention at all of Dahlberg advertising. (C.T. 61-65).

5. The Declaration of Gladys Faustine states that she saw and responded to a Dahlberg ad, but does not specifically identify or describe it and makes no complaint about it. (C.T. 66-68).

6. Finally, the Declaration of Minnie Carp states that she saw and responded to a piece of advertising, but does not indicate whether it was Dahlberg advertising. (C.T. 69-70).

To recapitulate, only two of the six appellees state that they saw and responded to Dahlberg advertising, and only one of the two indicates the content of such advertising. No appellee has complained about the nature or content of the advertising as such. Appellees' cause of action for fraud was directed strictly to the practices of an independent hearing aid dispenser, who was not the agent of Dahlberg.

Appellees also refer to a Department of Health, Education and Welfare report which is included in the record and which supposedly found that "misleading advertising and high pressure sales were prevalent in the hearing aid industry." (Motion, p. 7). Without regard to the hearsay nature of the report, which is purely a matter of California evidence law, we simply note that the report makes no reference to Dahlberg or its advertising.

Considering the utter and complete absence of any facts showing that Dahlberg's advertising had any harmful effect on anyone, appellees' argument that Dahlberg failed to produce evidence to the contrary, "although it was its duty to do so under California law" is totally without merit.[1]

ARGUMENT

I

THE DOCTRINE OF PRIMARY ADMINISTRATIVE JURISDICTION DOES NOT APPLY.

Appellees' argument that the F.D.A. has primary administrative jurisdiction over the pre-emption issue is without merit. The doctrine of primary administrative jurisdiction applies to two categories of cases: "[1] cases raising issues of fact not within the conventional experience of judges or

[1]An opponent's failure to file counter-affidavits on a motion for summary judgment admits the truth of the movant's affidavit, but does not relieve the movant from the burden of establishing evidentiary facts of every element necessary to entitle him to judgment. *Brewer v. Reliable Automotive Co.* (1966) 49 Cal.Rptr. 498, 240 C.A.2d 173; *American Soc. of Composers, Authors and Publishers v. Superior Court of Los Angeles County* (1962) 24 Cal. Rptr. 772, 207 C.A.2d 676; *House v. Lala* (1960) 4 Cal.Rptr. 366, 180 C.A.2d 412.

[2] cases requiring the exercise of administrative discretion." *Far East Conference v. U.S.* (1952) 342 U.S. 570, 574, 96 L.Ed. 576, 72 S.Ct. 492.

The pre-emption issue herein is clearly not an issue of fact outside the conventional experience of judges, and therefore the case does not fall within the first category. To the contrary the issue is one of law and wholly within the competence of the judiciary. See *Great N.R. Co. v. Merchants Elevator Co.* (1922) 259 U.S. 285, 66 L.Ed. 943, 42 S.Ct. 477; *Louisville & N.R. Co. v. F. W. Cook Brewing Co.* (1912) 223 U.S. 70, 56 L.Ed. 355, 42 S.Ct. 189.

As to the second category, it is necessary to have in mind that the pre-emption question herein involves two separate and distinct sub-issues: (a) whether the state law has been pre-empted; and (b) if it has been pre-empted, whether it should be exempted from pre-emption. As the following discussion will demonstrate, the first issue is a pure question of statutory construction which can be resolved by this Court, and no prior administrative determination is either necessary or appropriate. Only the second issue has been committed to the exercise of administrative discretion.

A. The question whether the statute has been pre-empted is for the Court and not for the F.D.A.

The doctrine of primary administrative jurisdiction requires a party first to resort to an administrative agency before he may sue for an adjudication involving a question within the competence of that agency. *Armour & Co. v. Alton R. Co.* (1941) 312 U.S. 195, 85 L.Ed. 771, 61 S.Ct. 498. The doctrine determines whether the court or the administrative agency should make the initial decision. *Texas &*

P.R. Co. v. Abilene Cotton Oil Co. (1907) 204 U.S. 426, 51 L.Ed. 553, 27 S.Ct. 350; 3, K. Davis, *Administrative Law Treatise*, sec. 19.01.

The Court should not apply the doctrine to the pre-emption question herein, for to do so the Court would have to extend it beyond all bounds revealed in prior decisions. First, Dahlberg did not initiate this litigation and therefore should not be required to "resort to" an administrative agency. Secondly, the "initial decision" has already been made. The Court of Appeal, acting in accordance with the views expressed by appellees, has rendered a decision that the state statute was not pre-empted. Dahlberg now seeks review of that decision. The case is therefore in an entirely different posture than one where no court decision has been rendered. (Cf. *Annotation, Primary Administrative Jurisdiction*, 38 L.Ed.2d 796, and cases collected therein.)

Appellees did not urge in the Court of Appeal that the question of whether the statute had been pre-empted should be left up to the F.D.A. It now argues this point for the first time in this Court. Dahlberg should not be denied review in this Court at the instance of parties who urged the decision below.

Thirdly, the question of whether the statute has been pre-empted is not actually pending before the F.D.A. No petition or application of any kind seeking to have the F.D.A. make such determination has ever been filed by any party. The only applications before the F.D.A. are from states such as California, seeking to have their statutes exempted from pre-emption.

Finally, and of utmost importance, the question whether the statute has been pre-empted is not within the jurisdiction of the F.D.A. The only question actually within its jurisdiction is whether the statute, having been pre-empted, should now be exempted from pre-emption upon application of the State of California. This distinction has been expressly recognized by the two other state courts which have had occasion to consider this problem. See *New Jersey Guild of Hearing Aid Dispensers, et al. v. Long* (1977) 75 N.J. 544, 384 A.2d 795, 809; *New York State Hearing Aid Society v. State of New York* (E.D.N.Y., March 10, 1978). The latter opinion specifically states that the statute may not be enforced unless and until an exemption is granted. (Motion, Ex. 2, p. 5).

B. A stay of the appeal is not required.

The question of whether the statute should be exempt from pre-emption is admittedly within the jurisdiction of the F.D.A. (21 U.S.C. § 360k(b)). Because the California application for exemption is currently pending before the F.D.A., the Court might be inclined to stay its hand until the F.D.A. has ruled upon the application. *Federal Power Com. v. Louisiana Power and Light Co.* (1972) 406 U.S. 621, 32 L.Ed.2d 369, 92 S.Ct. 1827. Here, however, there are several other considerations which impel the conclusion that the Court should not postpone its consideration of this appeal. Initially, the Court should consider the fact that neither of the parties to this appeal has initiated the proceeding before the F.D.A. The proceeding was initiated by an application of the State of California Department of Health, which was filed over two years ago. The application covers the entire Sherman Food, Drug and Cos-

metic Law and not just the portion of the subject statute which relates to hearing aids.

Of primary importance is the fact that the statute, even if exempt from pre-emption, would still be unconstitutional. The case is therefore akin to *Public Utilities Com. v. United States* (1958) 355 U.S. 534, 2 L.Ed.2d 470, 78 S.Ct. 446, in which the United States brought suit challenging the constitutionality of a California statute prohibiting carriers from transporting government property at rates other than those approved by the California Public Utilities Commission. The Court held that the doctrine of primary administrative jurisdiction did not apply because the constitutional issue was one which the Public Utilities Commission could not be expected to entertain. In so holding the Court stated:

> "But where the only question is whether it is constitutional to fasten the administrative procedure onto the litigant, the administrative agency may be defied and judicial relief sought as the only effective way of protecting the asserted constitutional right. In that posture the case is kin to those that hold that 'failure to apply for a license under an ordinance which on its face violates the Constitution does not preclude review in this Court of a judgment of conviction under such an ordinance.' *Staub v. Baxley*, 355 U.S. 313, 319, 2 L.Ed.2d 302, 309, 78 S.Ct. 277, and cases cited; *Thomas v. Collins*, 323 U.S. 516, 89 L.Ed. 430, 65 S.Ct. 315." (355 U.S. at 540).

Also, as stated in the separate opinion by Justice White (joined by Chief Justice Warren and Justice Brennan), in *Amalgamated Meat Cutters & Butcher Workmen v. Jewel Tea Co.* (1965) 381 U.S. 676, 14 L.Ed.2d 640, 85 S.Ct. 1596,

the doctrine of primary jurisdiction is not a doctrine of futility; it does not require resort to an expensive and merely delaying administrative proceeding when the case must eventually be decided on a controlling legal issue wholly unrelated to determinations for the ascertainment of which the proceeding is to be submitted to the agency.

Appellant submits that in the instant case, no purpose would be served by awaiting the decision of the F.D.A. as to whether the statute should be exempt. Even if the statute were held exempt, it would still be unconstitutional. Furthermore, appellant is being denied its constitutional right to advertise while awaiting the outcome of a very lengthy F.D.A. proceeding. The Court should therefore proceed with the hearing of this appeal without further delay. See *Ricci v. Chicago Mercantile Exchange* (1973) 409 U.S. 289, 34 L.Ed.2d 525, 93 S.Ct. 573 (Marshall, J. dissenting).

C. The appeal should not be dismissed on the basis of the primary administrative jurisdiction doctrine.

Even if the primary administrative jurisdiction doctrine were applicable, dismissal of the appeal would not be appropriate. Application of the doctrine generally results in a stay of the action rather than a dismissal, *United States v. Western R.R. Co.* (1956) 352 U.S. 59, 1 L.Ed.2d 126, 77 S.Ct. 161; *Amalgamated Meat Cutters & Butcher Workmen v. Jewel Tea Co.* (1965) 381 U.S. 676, 14 L.Ed.2d 640, 85 S.Ct. 1596; *International Brotherhood of Boilermakers, etc. v. Hardeman* (1971) 401 U.S. 233, 28 L.Ed.2d 10, 91 S.Ct. 609, reh. den. 402 U.S. 967, 29 L.Ed.2d 132, 91 S.Ct. 1607, particularly where there are rights which may

be saved by retaining the cause. *Mitchell Coal & Coke Co. v. Pennsylvania R. Co.* (1913) 230 U.S. 247, 57 L.Ed. 1472, 33 S.Ct. 916; *General American Tank Car Corp. v. El Dorado Terminal Co.* (1940) 308 U.S. 422, 84 L.Ed. 361, 60 S.Ct. 325, reh. den. 309 U.S. 694, 84 L.Ed. 1035, 60 S.Ct. 465. In *United States v. Michigan National Corp.* (1974) 419 U.S. 1, 42 L.Ed.2d 1, 5, 95 S.Ct. 10, the Court held that a stay of the action, rather than dismissal, would be proper because it could not be said "with assurance" that the Government would not be prejudiced by a dismissal. (419 U.S. at 5).

In the instant case, it would be prejudicial to appellant to dismiss the appeal because its right to present its First Amendment claim would thereby be lost. Appellees argue that if the F.D.A. should deny the state's application for exemption from pre-emption, appellant could successfully move to have the injunction vacated on the basis of change in law. *Sontag Chain Stores Co. v. Superior Court* (1941) 18 Cal.2d 92, 94-95, 113 P.2d 689. While it is true that appellant would have this remedy, there is also the possibility that the F.D.A. may grant the exemption, so that pre-emption would no longer be an issue. If in the meantime the appeal were to be dismissed, appellant would no longer have the opportunity to present the First Amendment issue to this Court.

II

THE STATUTE HAS BEEN PRE-EMPTED.

Appellant's Jurisdictional Statement sets forth the manner in which pre-emption occurred. Appellees nevertheless contend that pre-emption has not occurred and advance

several arguments in support of their contention. None of these arguments has any validity whatever.

A. Specific counterpart regulations have been adopted by the F.D.A.

Appellees first assert that the California law "would be pre-empted only when the F.D.A. had established 'specific counterpart regulations' applicable to the device." (Motion, p. 16). This is erroneous. The regulations, which speak in the disjunctive, state that:

> "State or local requirements are pre-empted only when the Food and Drug Administration has established specific counterpart regulations *or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.*" (21 *C.F.R.* § 808.1(d), emphasis added).

The meaning of "specific counterpart regulations," which is not a statutory term and not defined by the F.D.A., is not entirely clear. There is no specific federal regulation similar to Section 26463, but the federal regulations clearly reach the subject of hearing aid advertising and may well be deemed "counterpart" to Section 26463.

Notwithstanding this ambiguity, however, it is quite clear that there are in fact "other specific requirements applicable to [hearing aids] under the Act," and that the state requirement is divergent therefrom. In particular there is the requirement contained in 21 U.S.C. § 352(r) as to information which *must* be included "in all advertisements and other descriptive printed matter issued or

caused to be issued by the manufacturer, packer or distributor with respect to [the] device." The state law is clearly "different from" this federal requirement because it is impossible to comply with both. *Jones v. Rath Packing Co.* (1977) 430 U.S. 519, 51 L.Ed.2d 604, 97 S.Ct. 1305. See also *New Jersey Guild of Hearing Aid Dispensers, et al. v. Long, supra*, 75 N.J. 544, 384 A.2d 795, 812, in which the pre-sale testing requirement in the New Jersey law was held to have been pre-empted by the federal law because it would operate to create a prerequisite to the sale of a hearing aid that is "in addition to" that specified in the federal regulation even though not "different from" it.

B. The federal law and regulations are directly concerned with advertising.

Appellees also contend that the federal requirements are primarily concerned with labeling, rather than advertising, and that "the F.D.A. regulations totally ignore the field of hearing aid advertising." (Motion, p. 20). This is simply not so.

First, there is no true distinction between "labeling" and "advertising" in the context of this case. As heretofore noted, the term "advertisement" is broadly defined in the California Health and Safety Code as follows:

> "'Advertisement' means any representations, including, but not limited to, statements upon the products, its packages, cartons, and any other container, disseminated in any manner or by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase or use of any food, drug, device or cosmetic." (California Health and Safety Code Section 26002).

This definition would obviously cover a label used on the device or on the container for a device.

Secondly, the federal statute, 21 U.S.C. § 352(r), is not just concerned with "labeling." It is concerned with "all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to [the] device."

Finally, the F.D.A. regulations do speak of labeling, but not in the narrow sense suggested by appellees. As the Commissioner states:

> "The Food and Drug Administration (FDA) is establishing uniform professional and patient labeling requirements and conditions for sale of hearing aid devices. The regulations prescribe the types of information that must be included in the labeling to provide hearing professionals and patients with adequate directions for the safe and effective use of a hearing aid; . . . ." (42 Fed. Reg. 9286).

Directions for the safe and *effective* use of a hearing aid necessarily involve statements which are likely to induce its purchase, either directly or indirectly. Thus the regulations clearly reach "advertisements" within the meaning of California Health and Safety Code section 26002. Whether such directions also constitute "labeling" is simply not relevant to this appeal.

C. It is impossible to comply with both the state law and the federal law and regulations.

Appellees suggest that a hearing aid manufacturer can comply with both federal and state law by limiting its advertising to the simple statement that "hearing aids are used to amplify sound." (Motion, pp. 23, 25). This sug-

gestion only serves to demonstrate the futility of appellees' position and the absurdity of the state law as construed by the court below. A simplistic statement of this kind is not informative to the potential hearing aid user. In no sense can it be said to comply with 21 U.S.C. § 352(r) which requires advertising to contain "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications. . . ." In order to comply with the federal law, a manufacturer who intends to advertise must at least be free to tell the potential user: "If you are hard of hearing, then a hearing aid may help you to hear more clearly," or "If you have trouble hearing, then a hearing aid may compensate for your hearing loss." But such statements are precisely what the state law now forbids.

Appellees suggest that the manufacturer has a simple solution to his dilemma: don't advertise at all. This suggestion is totally unreasonable, contrary to the purpose of the federal law, contrary to the stated position of the F.D.A., and, most importantly, it flies in the face of the First Amendment. A manufacturer simply cannot be put to the choice of either violating federal law or remaining silent.

D. The California statute relates to the effectiveness of hearing aids as well as to the advertising thereof.

Appellees take the erroneous position that a state law will not be pre-empted unless it relates "to the safety or effectiveness of the device." (See 21 U.S.C. § 360k).[2] They argue that the California statute is not concerned with the safety or effectiveness of the device, but rather with sales practices, and therefore it is not pre-empted. There are two difficulties with this view. First, the California Court of Appeal has expressly recognized that the statute *does* relate to the effectiveness of hearing aids. As the Court of Appeal states in discussing the pre-emption issue herein, "[the statute] 'relates to the effectiveness' of hearing aids by prohibiting representations on this subject in copy which advertises them for sale." (J.S., p. 34). See also the portion of the opinion of the Superior Court discussing the purpose of the statute as relating to the "efficacy" of the device. (J.S., p. 41).

The other difficulty with appellees' view is that it involves a misreading of the federal statute. State law requirements which are different from or in addition to federal requirements are pre-empted if they relate "to the safety or ef-

---

[2]The F.D.A. also appears to share this mistaken view when it states in its latest pronouncement on the California statute:

> "The Commissioner is also proposing to exempt from pre-emption California's Health and Safety Code, section 26463 (m), which prohibits the advertising of any device represented to have any effect in diseases or disorders of the ear. The Commissioner especially seeks comments on this provision because to the extent that it relates to the safety and effectiveness of a hearing aid, it is more stringent that the FDA requirements. However, if the provision is not related to safety or effectiveness, but rather relates to other forms of consumer protection, it may not be pre-empted by section 521(a) of the act." (43 Fed.Reg. 33182).

fectiveness of the device *or to any other matter included in a requirement applicable to the device under this chapter.*" 21 U.S.C. § 360k(a) (emphasis supplied). Even if the state statute did not relate to the effectiveness of the device, it clearly relates to another matter included in a federal requirement, i.e., the advertising requirement of 21 U.S.C. § 352(r). Accordingly, it is also pre-empted on this latter basis.

E. The state statute is not to be deemed exempt from pre-emption.

Appellees' argument that the statute is automatically exempt because it is more stringent than the federal requirements is not correct. The fact that the state statute is more stringent means that the F.D.A. *may* grant an exemption, not that it is required to do so. (21 U.S.C. § 360k(b)).

F. Regulation of hearing aid advertising is within the jurisdiction of the F.D.A.

Appellees represent that the F.D.A. has found that ". . . regulation of hearing aid sales practices, including advertising, were [sic] not within the scope of its authority but would be left to the Federal Trade Commission. . . ." (Motion, p. 16; see also pp. 23-24). This is a misstatement of the law and of the F.D.A.'s position. What the F.D.A. actually said was, in sum and substance, as follows:

> *"Section 502(r) gives FDA jurisdiction for regulating certain specified advertising of restricted devices,* and the section concurrently removes FTC authority to apply the sanctions of court injunction or criminal penalties under sections 12 through 15 of the Federal Trade Commission Act to prevent these acts. It is the Commissioner's opinion, however, that section 502(r) limits FTC authority only to the extent specifically stated in the section, i.e., section 502(r) applies only to restricted devices and only to possible FTC use of court injunctions or criminal penalties to prevent false advertising relating to the items of information specified in section 502(r). Moreover, section 502(r) does not extend to, or in any way limit, any other authority of FTC related to the regulation of the sale of devices, such as the authority provided to FTC under section 5 of the Federal Trade Commission Act (5 U.S.C. 45) to prevent unfair or deceptive acts or practices.
>
> "In sum, it is the Commissioner's opinion that the net effect of section 502(r), as of the comparable provision under section 502(n) relating to prescription drugs, is to enable each agency to approach the regulation of restricted devices from the perspective of its particular statutory mandate. It is also the Commissioner's belief that both agencies will continue, as they have in the past, to work together in pursuit of their separate but closely related mandates. The Food and Drug Administration has long been aware of the FTC activities in the regulation of hearing aids that led to the FTC proposed rule, and the Commissioner believes these activities complement, rather than conflict with, this FDA regulation relating to labeling and conditions of sale of hearing aids. The Commissioner generally supports the FTC proposed rule and believes that the matters addressed therein are particularly within the FTC statutory mandate and expertise." (42 Fed.Reg. 9286, emphasis supplied).

As the foregoing statement indicates, the F.T.C. issued a proposed trade regulation rule in 1975 for the hearing aid industry. (See 40 Fed.Reg. 26646). The proposed rule dealt, *inter alia,* with advertising, but the F.T.C.'s jurisdiction

in this area is by no means exclusive. Appellees' claim that the F.D.A. has left the entire regulation of hearing aid advertising up to the F.T.C. (thereby abdicating its statutory responsibility) is in error.[3]

III

THE STATUTE INFRINGES UPON THE RIGHT TO FREEDOM OF SPEECH.

Appellees advance several arguments in support of their claim that no substantial free speech question is presented. Each of these arguments fails to meet the issue and should be rejected.

A. The Court of Appeal passed upon the issue.

Appellees argue in one breath that ". . . the court properly held that Dahlberg's advertisements fall outside the scope of the First Amendment." In the next breath they say that ". . . the court below correctly declined to rule on the constitutional issue raised here by appellant, and that issue is not properly before this Court." (Motion, p. 31).

Appellees' confusion is perhaps understandable because the Court of Appeal, after first stating that ". . . we need not reach this problem" (J.S., p. 31) went on to hold that (a) the advertisements before it were misleading and (b) "The injunction is thus proper." (J.S., p. 31). The obvious flaw in this holding is that the premise simply does not support the conclusion. A finding that certain pieces of advertising are misleading will obviously not support an injunction against *all* advertising of the same kind, without regard to its truth or falsity.

[3]The F.T.C. has never finally adopted any trade regulation rules for the hearing aid industry.

In any case, the Court of Appeal has certainly rendered a decision on the free speech issue, and appellant should not be denied review of that decision simply because the court used confusing language in its opinion or because it failed to meet the issue before it in a clear and forthright manner. It is not necessary that the state court's denial of the federal claim "shall have been put in direct terms. . . ." "If the necessary effect of the judgment has been to deny the claim, that is enough." *New York ex rel. Bryant v. Zimmerman,* 278 U.S. 63, 67. See also *Chambers v. Mississippi* (1973) 410 U.S. 284, 290, n. 3, 35 L.Ed.2d 297, 93 S.Ct. 1038; *Street v. New York* (1969) 394 U.S. 576, 582, 22 L.Ed.2d 572, 89 S.Ct. 1354.

B. There is no compelling state interest sufficient to justify the denial of free speech.

Appellees argue that there is a compelling state interest in regulating advertising in the health care area sufficient to justify the statute and the injunction. In support of these arguments they rely upon numerous lower court cases which pre-date this Court's decision in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.* (1976) 425 U.S. 748, 48 L.Ed.2d 346, 96 S.Ct. 1817, and therefore are not persuasive.

Appellees point with alarm at alleged "promotional gimmicks" which will create an "artificial demand" for hearing aids. These considerations have no basis in fact and are completely contrary to the philosophy of the *Virginia* case which favors the "free flow of commercial information." (425 U.S. at 763). Furthermore they ignore the fact that the F.D.A. regulations now require a medical evaluation by a licensed physician within six months before the pur-

chase of a hearing aid. The physician must provide the patient with a written statement indicating that the patient's hearing loss has been medically evaluated and that the patient may be considered a candidate for a hearing aid. The patient may waive the evaluation but only under specified conditions designed to protect against any possible overreaching by the hearing aid dispenser. (21 *C.F.R.* § 801.421).[4] This requirement, so greatly emphasized by appellees in their discussion of the pre-emption issue, but completely overlooked in respect to the free speech issue, virtually eliminates the potentially dangerous consequences of advertising envisioned by appellees.

C. Appellant's interest is not contrary to the interests of the hearing aid user.

Appellees assert that appella..., as a manufacturer, has a mere "pecuniary" interest in advertising which conflicts with the interest of the public. (Motion, p. 39). This charge is unfounded and unfair. When viewed in proper legal perspective the interests of the manufacturer and the potential hearing aid user are totally consistent, just as the interest of the pharmacist and the consumer in the *Virginia* case were totally consistent. Both will benefit from the free flow of commercial information. "... [W]e may assume that the advertiser's interest is a purely economic one. That hardly disqualifies him from protection under the First Amendment." (425 U.S. at 762).

---

[4]This regulation, unlike the *proposed* exemption of the California statute, became final and effective on August 25, 1977.

D. Appellant should not be required to apply for permission to advertise under Health and Safety Code Section 26465.

Appellees argue that appellant has no standing to raise the First Amendment issue because it has never submitted any proposed advertising to the California Department of Health as supposedly contemplated by Health and Safety Code Section 26465. Appellant has already demonstrated in its Jurisdictional Statement the constitutional defects in Section 26465, which operates in conjunction with Section 26463 as a prior restraint. (J.S., pp. 20-21, 25-26).

In addition, a careful examination of Section 26465 reveals that it could never even apply to hearing aid advertising. Under Section 26465, it is the drug or device which the Department must approve, not the advertising as such, and the Department may only authorize the drug or device to be advertised if it determines that it is safe and effective as "self-medication." In such case, it may be advertised as having "a curative or therapeutic effect." The F.D.A. has determined that a hearing aid is not a safe and effective device for self-medication. It is a "restricted device" which should be sold only to persons who have had a medical evaluation by a licensed physician resulting in a determination that they are candidates for a hearing aid. Furthermore, a hearing aid is not a curative or therapeutic device. It is a compensatory device. (Calif. Bus. and Prof. Code § 3305.) Accordingly, Section 26465 simply cannot apply to hearing aids or to their advertising and has no impact upon appellant's claim under the First Amendment.

CONCLUSION

The motion to dismiss or affirm should be denied, and the Court should note probable jurisdiction herein.

Dated: February 12, 1979.

MICHAEL P. CARBONE

JORDAN, LAWRENCE, DAWSON & CARBONE

Attorneys for Appellants Dahlberg Electronics, Inc., and Detection Sciences, Inc.